positive patients. Furthermore, in these patients, failure to achieve remission is mostly related to high PGA rather than to the persistence of joint inflammation. Altogether, these findings implicate that autoantibody-negative RA patients failing to achieve remission would require adjunctive tailored interventions rather than reinforcement of DMARD therapy.

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FRI0146

SURVIVAL OF JAK INHIBITORS: REAL-WORLD DATA FROM THE BIOBADASER III REGISTRY

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Background: JAK inhibitors (JAKi) have been recently authorized in the European Union. JAKi long-term performance in the clinical practice setting still needs to be assessed. Drug survival reflects a drug's effectiveness, safety, and tolerability; thus, it is an important measurement for real-world studies.

Objectives: To describe the pattern of use of JAKi in real-world dataset, and to analyze the drug survival as a group (tofacitinib+baricitinib).

Methods: Information was obtained from BIOBADASER III, an ongoing observational longitudinal multicenter cohort of patients with rheumatic diseases treated with biologic or targeted synthetic (b/ts) DMARDs in Spain. All subjects with current or previous JAKi use were included and followed until September 2018. Clinical characteristics of the patients were analyzed. Drug survival (overall, and for biologic-naïve and biologic-experienced patients) was determined using Kaplan-Meier analysis.

Table 1. Diagnoses of patients with JAKi treatment

Diagnosis (patients)	n (%)
Rheumatoid arthritis	138 (92.6)
Idiopathic juvenile arthritis*	3 (2.0)
Psoriatic arthritis	2 (1.3)
Undifferentiated spondyloarthritis*	2 (1.3)
Seronegative polyarthritis*	2 (1.3)
Ankylosing spondylitis*	1 (0.7)
Enteropathic arthritis*	1 (0.7)
Total	149 (100)

*off-label use.

Results: 149 patients, 75.2% women, were treated with JAKi, receiving a total of 152 cycles of treatment (50.7% tofacitinib, 49.3% baricitinib; 3 patients had both). The most frequent diagnosis was rheumatoid arthritis (RA, 92.6%), and there is a small number of off-label uses (6%), depicted at Table 1. Use on psoriatic arthritis is scarce (1.3%). Concomitant use of methotrexate (MTX) was registered in 68 patients (45.6%). Previous use of bDMARDs was high (n=124, 81.6%); drug survival rate for biologic-experienced patients was 81.7% and 78.7% at 6 and 12 months. None of the JAKi treatments in biologic-naïve patients (n=18, 18.4%) were discontinued during follow-up. Pooled survival rate of JAKi was 85.0% and 82.5% at 6 and 12 months (Figure 1). Discontinuation was seen in 19 treatments (12.5%); the reasons were inefficacy (n=15, 9.9%) or adverse events (n=4, 2.6%).

Figure 1. Overall survival of JAKi and for biologic-naïve and biologic-experienced patients

Conclusion: The current use of JAKi in Spain is mainly in RA and as 2nd line after bDMARDs. The use of JAKi in psoriatic arthritis is still scarce and a small group of patients are treated off-label. Less than half use combination therapy with MTX. Overall survival of JAKi is superior to 80% at 12 months. A longer follow-up is needed to continue analyzing the survival of JAKi in a real-world context.

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FRI0147

SAFETY AND EFFECTIVENESS OF UPADACITINIB OR ADALIMUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS: RESULTS AT 48 WEEKS FROM THE SELECT-COMPARE STUDY

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Background: In the SELECT-COMPARE study in rheumatoid arthritis (RA) patients (pts) with inadequate response to methotrexate (MTX), upadacitinib (UPA), a JAK1- selective inhibitor, was superior to placebo (PBO) or adalimumab (ADA) for treatment of signs & symptoms and for inhibition of radiographic progression vs PBO up to 26 weeks (wks). All pts were on stable background MTX. ¹

Objectives: To report safety and efficacy of UPA plus stable background MTX up to 48 wks in this phase 3 study.

Methods: Pts were randomized to once-daily (QD) UPA 15mg, PBO, or ADA 40mg every other wk, with all patients continuing background MTX. The study was double-blind for 48 wks. Between Wks14-26, pts were rescued (from PBO to UPA, UPA to ADA, or ADA to UPA) if there was <20% improvement in tender/swollen joint count (Wks 14/18/22) or if Clinical Disease Activity Index (CDAI) was >10 (Wk26); all PBO pts who were not rescued were switched to UPA at Wk 26. Efficacy was analyzed by randomized group. Non-responder imputation (NRI) was used for binary endpoints for rescue prior to Wk26. Last observation carried

forward (LOCF) was used for continuous endpoints and binary endpoints after Wk26. Treatment-emergent adverse events (AE) per 100 pt yrs (PY) were summarized up to July 6 2018 for pts with any exposure to ADA or UPA.

Results: In SELECT-COMPARE, 1629 pts were randomized at BL. Among 651 pts randomized to UPA, 38.7% were rescued between Wks 14-26; of those who remained on UPA, 86% completed Wk 48, while 5.8% and 0.3% discontinued study drug between BL and Wk 48 due to AE and lack of efficacy (LoE), respectively. Among 327 pts randomized to ADA, 48.6% were rescued between Wks 14-26; of those who remained on ADA, 76% completed Wk48, while 13.1% and 0 discontinued study drug between BL and Wk48 due to AE and LoE, respectively. The cumulative exposures were 1243.3 and 467.8 PYs for UPA and ADA, respectively. At Wk26, and Wk48, significantly more pts in the UPA vs ADA group achieved ACR20/50/70, low disease activity and remission (Table 1); this was also true for visits between Wks 26 and 48. Similarly, improvements in pain and function were significantly greater in the UPA vs ADA group through Wk48. At Wk26, there was significantly less radiographic progression for UPA vs PBO, which was maintained through Wk48 (based on linear extrapolation). Adverse events are reported in Table 2 (in events per 100 PY). The rate of AE leading to discontinuation was higher with "any ADA" vs "any UPA", while the rate of Herpes zoster was higher with "any UPA" exposure.

Conclusion: UPA continued to demonstrate superior clinical and functional responses vs ADA through Wk48. Inhibition of structural joint damage with UPA was also maintained through 48 wks vs PBO. Safety was consistent with observations in the first 26 wks.¹

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Table 3									
Endpoint	Week 12			Week 26			Week 48		
	FCO n=451	ADA n=451	Ratio	FCO n=451	ADA n=451	Ratio	FCO n=451	ADA n=451	Ratio
ACR20 (%)	38.7	24.1	1.61	38.7	24.1	1.61	38.7	24.1	1.61
ACR50 (%)	15.1	8.2	1.84	15.1	8.2	1.84	15.1	8.2	1.84
ACR70 (%)	5.8	2.1	2.76	5.8	2.1	2.76	5.8	2.1	2.76
Low disease activity (%)	14.1	8.2	1.72	14.1	8.2	1.72	14.1	8.2	1.72
Remission (%)	5.8	2.1	2.76	5.8	2.1	2.76	5.8	2.1	2.76
Discontinuation due to AE (%)	5.8	0.3	19.33	5.8	0.3	19.33	5.8	0.3	19.33
Discontinuation due to LoE (%)	0.3	0.0	>100	0.3	0.0	>100	0.3	0.0	>100
Discontinuation due to unknown (%)	0.0	0.0	>100	0.0	0.0	>100	0.0	0.0	>100
Discontinuation due to other (%)	0.0	0.0	>100	0.0	0.0	>100	0.0	0.0	>100
Discontinuation due to death (%)	0.0	0.0	>100	0.0	0.0	>100	0.0	 									